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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,226	09/16/2003	John R. Boehringer	B1256/20003 (11)	2118

3000 7590 03/31/2010

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/31/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,226	BOEHRINGER ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,26,28,30-33 and 35-42* is/are pending in the application.

4a) Of the above claim(s) *1-22,28,30-33,35-38 and 40-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,26,28,39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 23, 26, 28 and 39 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

Claim Objections

2. Claim 23 is objected to because of the following informalities: the phrases "the interior of the wound a source of suction" in item "a", "wound packing is located source of suction" in item "b", and "to cause said wound packing an anisotropic wound packing" in item "c" appear to contain a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 23, 26, 28 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morykwas et al (see PTO-892 form for full citation) in view of Hoover (U.S. Patent No. 2,524,195).

With respect to **claim 23:** Morykwas discloses a medical device for treating a wound of a patient, the wound necessarily having sides, an interior and at least one wound axis extending generally parallel to the skin of the patient contiguous with the wound. The device is arranged for encouraging the contraction of the wound along said the at least one wound axis. With regard to item a), the device comprises an enclosure in the form of an adhesive drape for engaging the skin of the patient over and around the wound and having an opening accepting tubing for communication with the interior of the wound and a source of suction, an adjustable vacuum pump, arranged for applying continuous suction to the wound (Page 554, ¶1). With regard to item (b), the device comprises an enclosure coupled to a separate anisotropic wound packing formed of saline-moistened gauze, said wound packing being arranged to be placed in the interior of the wound (referred to by Morykwas as a "defect"), said enclosure being arranged to be separately placed over said wound packing after said wound packing has been placed in the interior of the wound to produce an enclosed interior space in the wound in which said wound packing is located, wherein the enclosure is coupled to a source of suction arranged for maintaining continuous suction on the wound by engaging the skin of the patient around the wound. With regard to (c), the device comprises a source of suction coupled to said enclosure to directly apply continuous suction via said opening in said enclosure to said enclosed interior space to said anisotropic wound packing arranged to preferably collapse inward along said at

least one axis inasmuch as this is necessarily what occurs when suction is applied to open-cell foam having one dimension larger than the other as in the foam disclosed by Morykwas, said wound packing thus necessarily being arranged to be placed in the wound to encourage preferential the contraction of the wound along the at least one wound axis when continuous suction is applied to the wound.

With further regard to item b), Morykwas discloses packing a wound/defect with saline-moistened gauze but does not disclose that the gauze packing is formed of at least one roll of gauze as claimed. Hoover discloses a wound packing comprising at least one roll of gauze 16', said at least one roll necessarily having a longitudinal axis and at least one radial axis and also necessarily comprising plural spiral layers wound about said longitudinal axis as this is the structural nature of a roll, said wound packing being arranged to be placed in the interior of the wound, in this case a bodily cavity experiencing hemorrhaging, with said at least one radial axis facing a side of the wound and extending parallel to the at least one wound axis inasmuch as Hoover discloses that the cavities are e.g. nasal, uterine and throat, all of which would require a vertical orientation of the gauze roll. As Hoover discloses that such rolls of gauze are known and that providing at least one roll of gauze prevents dangerous loss of blood due to said hemorrhaging, it would be obvious to one of ordinary skill in the art to modify the device of Morykwas such that the saline-moistened gauze is in the form of at least one gauze roll oriented vertically and meeting the claim limitations as to positioning of the radial and longitudinal axes of the roll and as disclosed by Hoover to prevent dangerous loss of blood due to hemorrhaging which also occurs in wounds such as that disclosed by Morykwas. The device of Morykwas as modified by Hoover thus renders the limitation "said enclosure being arranged to be separately placed over said wound packing after said wound packing has been placed in the interior of the wound to produce an enclosed interior space in the wound in which said wound packing is

located" unpatentable. Similarly, with further regard to item (c) the device of Morykwas as modified by Hoover renders the limitation "an anisotropic wound packing formed of a spirally wound cylindrically configured winding of gauze" unpatentable. Further, a spirally wound roll of gauze such as that disclosed by Hoover by nature is arranged to preferably collapse inward along said at least one in radial axis directions due to the anisotropic nature of a roll-shaped entity with respect to applied force and response as a result of its unequal dimensions. Thus, the device of Morykwas as modified by Hoover also renders the limitation "said wound packing being arranged to be placed in the wound to encourage preferential contraction of the wound along the at least one wound axis when continuous suction is applied to the wound" unpatentable.

With respect to **claim 26:** It is the examiner's position that both Morykwas and Hoover fairly suggest a wound packing comprising a plurality of said rolls, inasmuch as it would be readily apparent to one of ordinary skill in the art to provide more than one roll of gauze according to the Hoover disclosure, especially in light of Morykwas' and Hoovers' disclosure of bleeding/hemorrhaging wounds, as additional gauze rolls will provide additional absorbent capability and reduce the frequency of changing the packing. Morykwas discloses saline-moistened gauze, which could be more than one unit of gauze, but does not explicitly disclose a plurality of rolls with their respective longitudinal axes disposed generally parallel to each other in the interior of the wound. Hoover discloses a roll of gauze inserted via a dispenser to a hemorrhaging body cavity. Since all of the cavities explicitly disclosed by Hoover would require a vertical orientation of the gauze, which necessarily results in a plurality of rolls with their respective longitudinal axes disposed generally parallel to each other in the interior of the wound, it would be obvious to one of ordinary skill in the art to modify the device of Morykwas

such that the wound packing comprises a plurality of gauze rolls as disclosed by Hoover arranged vertically to prevent dangerous loss of blood.

With respect to **claim 28:** The enclosure disclosed by Morykwas is arranged to create a substantially air-tight seal with the skin of the patient.

With respect to **claim 39:** The method of Morykwas as modified by Hoover renders all of the limitations of claim 39 unpatentable for reasons stated in detail to follow and thus renders the limitation "a method of controlling the direction of contraction of a wound of a patient" unpatentable. Morykwas discloses a wound necessarily having sides, an interior and at least one wound axis extending generally parallel to the skin of the patient contiguous with the wound.

With regard to step (a), Morykwas discloses the step of providing a separate anisotropic wound packing formed of saline-moistened gauze. With regard to step (c), Morykwas discloses providing a separate enclosure, an adhesive drape, engaging the skin of the patient over and around the wound, said enclosure having an opening in communication with the interior of the wound to accommodate suction tubing extending between a wound dressing and a vacuum pump. With respect to step (d), Morykwas discloses sealing said wound with said anisotropic wound packing therein to produce an enclosed interior space in the wound in which said wound packing is located contiguous with said wound. With respect to step (e), Morykwas discloses providing a source of suction, an adjustable vacuum pump, coupled to said enclosure to directly apply continuous suction via said opening in said enclosure to said enclosed interior space and said wound and maintaining suction.

With further regard to step (a), Morykwas discloses providing a separate anisotropic wound packing formed of saline moistened gauze. However Morykwas does not disclose that the gauze is in the form of at least one roll of gauze. Hoover discloses providing a wound packing comprising at least one roll of gauze **16'**, said at least one roll necessarily having a longitudinal axis and at least one radial axis and also necessarily comprising plural spiral layers wound about said longitudinal axis as this is the structural nature of a roll. As Hoover discloses that such rolls of gauze are known and that providing at least one roll of gauze prevents dangerous loss of blood due to said hemorrhaging, it would be obvious to one of ordinary skill in the art to modify the device of Morykwas such that the saline-moistened gauze is in the form of at least one gauze roll oriented vertically and meeting the claim limitations as to radial and longitudinal axes of the roll and as disclosed by Hoover to prevent dangerous loss of blood due to hemorrhaging which also occurs in wounds such as that disclosed by Morykwas. *A spirally-wound, cylindrically-configured roll of gauze such as that disclosed by Hoover by nature is arranged to preferably collapse inward along said at least one in radial axis directions due to the anisotropic nature of a roll-shaped entity with respect to applied force and response as a result of its unequal dimensions, thus that limitation of claim 39, step (a) is rendered unpatentable by the method of Morykwas as modified by Hoover.*

With regard to step (b), Morykwas does not disclose at least one roll of gauze. Hoover discloses placing said anisotropic wound packing in said wound, in this case a bodily cavity experiencing hemorrhaging, with said at least one radial axis facing a side of the wound and extending parallel to the at least one wound axis inasmuch as Hoover discloses that the cavities are e.g. nasal, uterine and throat, all of which would require a vertical orientation of the gauze roll. As Hoover discloses that such rolls of gauze are known and that providing at least one roll of gauze prevents dangerous loss of blood due to said hemorrhaging, it would be obvious to

one of ordinary skill in the art to modify the device of Morykwas such that the saline-moistened gauze is in the form of at least one gauze roll oriented vertically and meeting the claim limitations as to positioning of the radial and longitudinal axes of the roll and as disclosed by Hoover to prevent dangerous loss of blood due to hemorrhaging which also occurs in wounds such as that disclosed by Morykwas. As the roll of gauze disclosed by Hoover is anisotropic with respect to forces applied and different responses to that force along the radial and longitudinal axes, the wound packing roll of gauze disclosed by Hoover is necessarily in a predetermined orientation (i.e. vertical) to allow a controlled strain to be imposed on the wound tissue.

Similarly, with respect to step (e), the cylindrical structure of the roll of gauze disclosed by Hoover imparts the anisotropic nature of the roll with respect to suction force applied, and due to the unequal dimensions of the roll, the roll wound-packing is necessarily caused to preferably collapse inward along said at least one radial axis to encourage the contraction of the wound along the at least one wound axis. The radial axis is shorter, thus the same suction force is distributed over a smaller dimension, thus the pressure is greater along the radial axis, causing the inward collapse along that axis. It is for these reasons that the method of Morykwas as modified by Hoover renders step “e” unpatentable.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761